ATTORNEY'S DOCKET CS-120
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	)	Group Art Unit: 1642
	)	
TALOR	)	Examiner: Gary B. Nickol
	)	
Serial No. 10/611,914	)	
	)	
Filed: July 03, 2003	)	

For: **A METHOD OF PRE-SENSITIZING CANCER PRIOR TO TREATMENT WITH RADIATION AND/OR CHEMOTHERAPY AND A NOVEL CYTOKINE MIXTURE**

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This is in response to the Restriction Requirement bearing a mail date of February 27, 2004. The one-month shortened statutory period for response is set to expire on March 27, 2004. Accordingly, this Response is timely filed.

SUMMARY OF RESTRICTION REQUIREMENT

The Restriction Requirement states as follows:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1 (claims 1-12) drawn to a **method** for pre-sensitizing cancer prior to therapeutic treatment comprising administering a therapeutically active amount of specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ and GM-CSF to IL-2

Group 2 (claims 13-23) drawn to a **method** for inducing tumor cells into a cell cycle selected from the group of G_1, S, G_2 and M comprising administering a therapeutically active amount of specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ and GM-CSF to IL-2.

Group 3 (claims 24-27) drawn to a serum-free and mitogen-free cytokine mixture comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ and GM-CSF to IL-2 and pharmaceutical composition thereof.

Group 4 (claims 26-28) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **IL-3** to IL-2.

Group 5 (claims 26-27 and 29) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **IL-6** to IL-2.

Group 6 (claims 26-27 and 30) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **IL-8** to IL-2.

Group 7 (claims 26-27 and 31) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **IL-1α** to IL-2.

Group 8 (claims 26-27 and 32) drawn to pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **IL-10** to IL-2.

Group 9 (claims 26-27 and 33) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **IL-16** to IL-2.

Group 10 (claims 26-27 and 34) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **G-CSF** to IL-2.

Group 11 (claims 26-27 and 35) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **TNF-β** to IL-2.

Group 12 (claims 26-27 and 36) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **MIP-1α** to IL-2.

Group 13 (claims 26-27 and 37) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **MIP-1β** to IL-2.

Group 14 (claims 26-27 and 38) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-

γ, GM-CSF and **RANTES** to IL-2;

Group 15 (claims 26-27 and 39) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and EGF to IL-2.

Group 16 (claims 26-27 and 40) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF, and **PGE_2** to IL-2.

Group 17 (claims 26-27 and 41) drawn to a pharmaceutical composition for use in treating cancer comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, GM-CSF and **TxB_2** to IL-2.

PROVISIONAL ELECTION

Applicant elects with traverse Group 3 (claims 24-27) drawn to a serum-free and mitogen-free cytokine mixture comprising specific ratios of cytokines selected from the group of IL-1β, TNF-α, IFN-γ, and GM-CSF to IL-2.

In the event the Restriction is not overcome, Applicant preserves the right to pursue the subject matter of the un-elected claims in later applications.

TRAVERSAL

Applicant respectfully traverses the Restriction Requirement

to Groups 1-17 and in particular to Groups 3-17 because Groups 3-17 are all drawn to the same composition claims 24-41 and further contain the claims limitations of independent claim 24.

Although the Restriction Requirement states that Groups 3-17 are separate and distinct, Applicant notes that Groups 3-17 contain all same essential characteristics of a single disclosed embodiment; namely the limitations of independent claim 24.

Turning to the rule of law, binding precedent clearly states that a Restriction Requirement should never be made where the claims of an application define the same essential characteristics of a single disclosed embodiment of the invention. MPEP §806.03.

Although the Office Action makes the assertion that the alleged distinctness imparted by each of the molecules IL-3, IL-6, IL-1α, requires restriction, Applicant notes the additional rule that claims alleged to be drawn to different species must contain mutually exclusive limitations defining those allegedly different species. MPEP §806.04(f). In other words, claims to be restricted to different species must contain within the language of the claims the mutually exclusive limitations for those species. However, the presently claimed molecules IL-3, IL-6, IL-1α, etc. of the dependent claims do not impart mutually exclusive limitations as is suggested by the Restriction Requirement.

Moreover, **each and every one** molecules alleged to be drawn to

the Groups 3-17 are **all** classified in Class 514, Subclass 2 or Class 530, Subclass 352 as noted by the Restriction Requirement. Therefore, there is no undue burden to search the sub-species of IL-3, IL-6, IL-1α, etc. given that each and every one of them is within the same Class and Subclass. It is facially improper to conclusively determine distinctness based on the Patent Classification Manual. See Applied Materials v. Advanced Semiconductor Materials, 40 USPQ2d 1481 (Fed. Cir. 1996) (holding that "[T]he grounds for restriction are **not** solely dependent on separate classification").

Applicant notes that an intensive study of the prior art within the same Classes and Subclasses was conducted pursuant to the requirements for a "Petition to Make Special", the results of which are provided in the previously filed "Petition to Make Special" and the "Discussion of Cited References" submitted herewith.

Finally, Applicant notes that a filing fee was paid for an examination of the claims drawn to a single invention in this application. If examination is refused for Groups 3-17, Applicant will be forced to file unnecessary divisional applications for each and every one of the specific dependent molecules. This would be unnecessarily redundant and unfairly force Applicant to pay duplicative fees for subject matter which can easily be searched

within the same Class and Subclass.

On the other hand, if the Examiner does not find the present traversal persuasive, Applicant respectfully remind the Examiner that a reasonable number of species should *sua sponte* be added back into the application upon allowance of the putative genus claim.

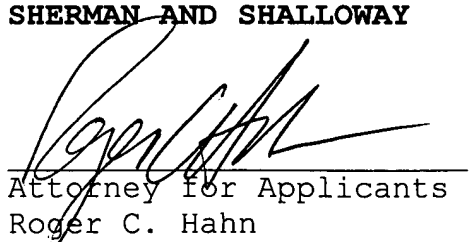
Accordingly, Applicant respectfully requests that the Restriction be withdrawn.

CONCLUSION

In view of the foregoing, Applicant respectfully requests the Examiner to reconsider and withdraw the Restriction Requirement and to examine all of the claims pending in this application or at the very least Groups 3-17 claims. If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

SHERMAN AND SHALLOWAY



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